Integrating the Healthcare Enterprise

IHE Radiology
Technical Framework Supplement

Reject Analysis & Monitoring (RAM)

Revision 1.0 – Draft for Public Comment

For review and comment only.

DO NOT implement this public comment version.

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Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE Radiology Technical Framework V20.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on March 8, 2024 for Public Comment. Comments are invited and can be submitted at https://www.ihe.net/Radiology_Public_Comments. In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by April 7, 2024.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text ~~**bold strikethrough**~~. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at IHE.net.

Information about the IHE Radiology domain can be found at IHE Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at Profiles and IHE Process

The current version of the Radiology Technical Framework can be found at Radiology Technical Framework.

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Introduction to this Supplement

This supplement adds a Reject Analysis & Monitoring Profile to record, distribute, and analyze information about images that have been rejected or otherwise flagged as having quality issues.

The profile standardizes storage, query, and retrieval of Rejection Notes and Quality Notes encoded as DICOM Key Object Selection (KOS) instances. It is intended to support capturing quality issues at the time of acquisition, and/or during subsequent QA and image reporting steps. The transactions follow a similar pattern to the IHE Radiation Exposure Monitoring Profile (REM), and the IHE Contrast Administration Monitoring Profile (CAM).

The profile also specifies Image Manager / Image Archive behaviors when the Rejection Note indicates the referenced images are non-diagnostic, to avoid visibility of rejected images in clinical workflow, referred to as "sequestration". The specification builds on similar behaviors described in the Image Object Change Management (IOCM) supplement. This is intended to facilitate removing non-diagnostic images from the clinical workflow but keeping them available for the quality improvement workflow.

TODO

- Add text to RAD-30 so that the IM/IA doesn't hide the rejection notes. – also in RAD-66
- Maybe find a way to work "Quality" into the Profile Name
- Poke modality subcommittees at AAPM (Kevin L) and DICOM WGs/EFOMP (Kevin O) for feedback on the different modality codes during Public Comment. And Service groups at vendors.
- Consider migrating the code tables into PS3.16 formally via a DICOM CP and then we just reference the CID.
- Google "reject analysis" to see if there are any interesting articles to mine for best practices to mention in Concept section (and potentially overlooked requirements)
- Why did CID 7011 have VM=1 in Sup59? Ask David? Find author. OK to allow multiple since prior row does?
- Do we need to add text to IOCM explaining that in the case of wrong worklist/patient, the original images would get sequestered, but typically new instances with the correct patient information would be created (and read even though not ordered).
- Review/limit divergent synonyms in the codes: unacceptable, inappropriate, suboptimal, poor, under, incorrect, …
- Confirm that all/most of the detailed reason codes clearly match to only one broad reason.

Open Issues

1. Are the general and modality-specific codes in X.1.1.1.* adequate for all modalities?

   Specifically, submission of modality-specific codes for each modality is requested.

2. Should we encode Detailed reasons and have receiver roll-up instead of encoding Broad?

   One of the reasons for the Broad codes was to have something that would be readily comparable between sites since they might be inclined to specialize and extend their fine codes.

3. Do we need to discuss how to retract a rejection?

   IOCM and specifically IHE RAD CP243 introduce the concept of rejected in error. When this is communicated to the SCP, they are expected to make a "best effort" to unreject/ retract, but it is not a guaranteed process. This Profile implicitly inherits this defined process and behavior by referencing IOCM. An example use case involves rejecting an image of an uncooperative patient then subsequently determining the initially rejected image is the best that is likely to be obtained and may prove adequate. It is also possible the "reject" button might be clicked mistakenly, perhaps instead of "quality issue" and it would be inappropriate to repeat the acquisition to remedy a user interface issue. Or the wrong image(s) might be selected when rejecting. If a tech has excessive quality standards, the clinician might find and recall an image determined to be adequate and used in the report (meaning the image should follow normal medicolegal retention policies.

4. Should we remove the requirement & guidance about sending to a Reject PACS? (QA Archive?)

5. Is the Code Meaning for each of the reason codes sufficiently clear and concise?

   These may appear in dropdown menus for technologists to select, so they need to be concise and data quality will benefit if they are clear.

6. Should we reduce some (or all) of the Rejected for Quality Issue material from IOCM that is now addressed (in more detail) here?

   If yes, what timeline (IOCM is Final Text, this will initially be TI).
   Might be tricky to migrate the sequestration into RAM if QI is not in IOCM.

Closed Issues

1. For non-reject quality issues do we expand RAD-66, use RAD-29, or make new?
   A: Use RAD-29 and RAD-66

Add text to RAD-66 and RAD-29 to cover reject analysis as needed.
Keep it easy for IM/IA (and modalities) to implement both IOCM and RAM.

2. Should we include KOS tagging of images as "good/OK"?
   A: No.

   While this would provide positive confirmation that a review of the images occurred and no issues were found, in practice it is unlikely to be done/used and it would generate a lot of instances/clutter. If there is a need to establish a "denominator" for rejection rates, a rough estimate can be established based on a census of studies/images.

3. Should Storage Commitment of the Reject/Quality Notes be required on the Reporter?
   A: Yes.

   For patient safety reasons, it is important to get confirmation from the Image Manager / Image Archive for Rejection Notes at least.

IHE Technical Frameworks General Introduction

The IHE Technical Frameworks General Introduction is shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to this document where appropriate.

9 Copyright Licenses

IHE technical documents refer to, and make use of, a number of standards developed and published by several standards development organizations. Please refer to the IHE Technical Frameworks General Introduction, Section 9 - Copyright Licenses for copyright license information for frequently referenced base standards. Information pertaining to the use of IHE International copyrighted materials is also available there.

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IHE Technical Frameworks General Introduction Appendices

The IHE Technical Framework General Introduction Appendices are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

Appendix A – Actors

*Add the following **new or modified** actors to the IHE Technical Frameworks General Introduction Appendix A:*

New (or modified) Actor Name	Definition
Quality Reporter	Flags medical images as having quality issues and/or being rejected.
Quality Analyzer	Consumes quality/reject information and supports QA analysis processes.

The table below lists *existing* actors that are utilized in this profile.

Complete List of Existing Actors Utilized in this Profile

Existing Actor Name	Definition
Image Manager	Manages and provides access to stored imaging objects.
Image Archive	Provides long term storage of imaging data such as images, measurements, presentation states, and manifests (e.g., a PACS).

Appendix B – Transactions

*Add the following **new or modified** transactions to the IHE Technical Frameworks General Introduction Appendix B:*

New (or modified) Transaction Name and Number	Definition
Key Image Note Stored [RAD-29]	**Send a list of image references and the label or note applied to those images.** ~~**An Acquisition Modality or an Image Creator sends a Key Image Note to the Image Archive**~~
Rejection Note Stored [RAD-66]	~~**Create and s**~~**S**end a ~~**manifest referencing**~~**list of** image **references** **and the reason they are removed from clinical use**~~**that are rejected for quality or patient safety reasons, rejected for incorrect modality worklist selection, or deleted due to data retention expiration. The manifest can be used to hide or provide rejected images later in routine use, based on specific configuration**~~.

Appendix D – Glossary

*Add the following **new or modified** glossary terms to the IHE Technical Frameworks General Introduction Appendix D:*

New (or modified) Glossary Term	Definition
Reject Analysis	Analysis of sets of images that have been identified as non-diagnostic or having some quality issue. This typically includes compiling statistics and identifying underlying causes as part of a quality improvement program.

Volume 1 – Profiles

Add new Section X

X Reject Analysis & Monitoring (RAM) Profile

The RAM Profile centralizes recording of details when images are rejected or otherwise flagged as having quality issues and making those details available for subsequent analysis.

Reject Analysis is an important part of a departmental quality system. Rejected images represent not just inefficient use of equipment, staff, and patients time, but can also involve obstructed patient care and unnecessary exposure to radiation. Images that are not rejected but still have quality issues represent an opportunity to improve the quality of imaging and patient care.

The Profile requires Image Manager / Image Archives to avoid making rejected images visible for query and retrieval, a behavior referred to as "sequestration". This is essentially the same behavior described in the Image Object Change Management (IOCM) Profile. This is intended to facilitate removing non-diagnostic images from the clinical workflow but keeping them available for the quality improvement workflow via a separate access mechanism.

While radiography has served as the driving use case, and some of the text specifically describes radiography, quality codes are provided for a variety of modalities and the profile is intended to be broadly applicable.

While the profile ensures robust sets of rejection records are readily available to Quality Analyzers, it does not mandate any specific reporting or analysis. Such choices are left to product designers and their customers. With the full details of rejections in hand, features to promote patient safety and healthcare quality should be easily provided.

X.1 RAM Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A. IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at https://profiles.ihe.net/GeneralIntro/index.html.

Figure X.1-1 shows the actors directly involved in the RAM Profile and the relevant transactions between them.

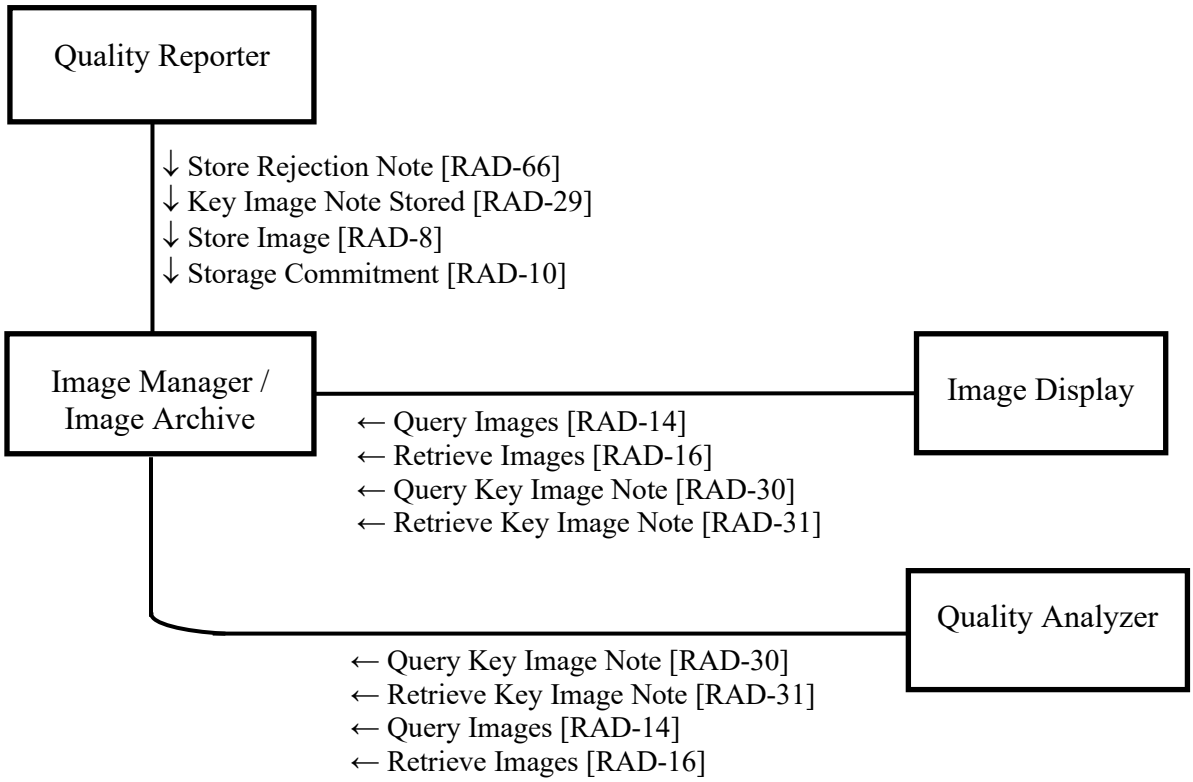


Figure X.1-1: RAM Actor Diagram

285 Table X.1-1 lists the transactions for each actor directly involved in the RAM Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

Table X.1-1: RAM Profile – Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
Quality Reporter	Store Rejection Note [RAD-66]	Initiator	R	RAD TF-2: 4.66
	Key Image Note Stored [RAD-29]	Initiator	R	RAD TF-2: 4.29
	Store Image [RAD-8]	Initiator	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	Initiator	R	RAD TF-2: 4.10
Quality Analyzer	Query Key Image Note [RAD-30]	Initiator	R	RAD TF-2: 4.30
	Retrieve Key Image Note [RAD-31]	Initiator	R	RAD TF-2: 4.31
	Query Images [RAD-14]	Initiator	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	Initiator	R	RAD TF-2: 4.16
Image Manager / Image Archive	Store Rejection Note [RAD-66]	Responder	R	RAD TF-2: 4.66
	Key Image Note Stored [RAD-29]	Responder	R	RAD TF-2: 4.29
	Store Image [RAD-8]	Responder	R	RAD TF-2: 4.8

Actors	Transactions	Initiator or Responder	Optionality	Reference
	Storage Commitment [RAD-10]	Responder	R	RAD TF-2: 4.10
	Query Key Image Note [RAD-30]	Responder	R	RAD TF-2: 4.30
	Retrieve Key Image Note [RAD-31]	Responder	R	RAD TF-2: 4.31
	Query Images [RAD-14]	Responder	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	Responder	R	RAD TF-2: 4.16
Image Display	Query Images [RAD-14]	Initiator	R	RAD TF-2: 4.14
	Retrieve Images [RAD-16]	Initiator	R	RAD TF-2: 4.16
	Query Key Image Note [RAD-30]	Initiator	O	RAD TF-2: 4.30
	Retrieve Key Image Note [RAD-31]	Initiator	O	RAD TF-2: 4.31

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in RAD TF-2 Transactions. This section documents any additional requirements on profile's actors.

X.1.1.1 Quality Reporter

Quality Reporters capture and distribute information about images that have been determined to be non-diagnostic (i.e. rejected) for some reason, or have been determined to have quality issues that may need to be tracked and addressed as part of an image quality program. Such information is encoded in DICOM Key Object Selection (KOS) instances.

Notes: 1. Workflow-oriented rejections, such as (113038, DCM, "Incorrect Modality Worklist Entry") are addressed by the Image Object Change Management (IOCM) Profile. A Quality Reporter that supports the RAM Profile will often find it useful to support the IOCM Profile in parallel. See Section X.6 RAM Cross-Profile Considerations.

2. Warm-up exposures, phantoms, and other non-patient images are identified by the Quality Control Subject (0010,0200) attribute and/or the Quality Control Image (0028,0300) attribute in the image header, not by modelling them as a quality defect using a KOS. Using those attributes, such images would be represented in neither the numerator nor the denominator of the quality analyses.

Systems that might implement a Quality Reporter include acquisition modalities, QA workstations, and reporting systems, to support recording quality issues identified at acquisition time, during a QA step, or during reporting, respectively.

The Quality Reporter shall store the KOS instance(s) to the primary Image Manager / Image Archive in the Study corresponding to the modality images to which they apply.

When the referenced images should be removed from clinical use, the Quality Reporter shall use Rejection Note Stored [RAD-66] with a Document Title value of (113001,DCM,"Rejected for Quality Reasons").

When a quality issue has been identified but the referenced images should not be removed from clinical use, the Quality Reporter shall use Key Image Note Stored [RAD-29] with a Document Title value of (113010,DCM,"Quality Issue")

Each Rejection Note and Quality Note shall include one Broad Reason code value in the Document Title Modifier. Additional Detailed Reason code values that fall under the Broad

Reason code may be included in the Document Title Modifier if known. Broad Reason codes are provided in Table X.1.1.1.1-3. Detailed Reason codes are provided in Table X.1.1.1.1-4 and in subsequent modality-specific sections. If multiple Broad Reason codes apply to the same image(s), or if there are both Rejection issues and Quality issues for the same image(s), then the Quality Reporter will create multiple KOS.

Most Reason Codes represent observable issues in the images. The underlying cause of the issue may or may not be known when the issue is observed. Rather than including codes that represent a suspected cause, it is better to record the observed issues in the codes, which facilitates analysis, and instead include possible causes of which the technologist is aware in the Key Object Description. Determination/confirmation of the cause is left until later analysis.

The Quality Reporter shall be capable of recording a free text comment in the Key Object Description (Row 7 of DICOM PS3.16 TID 2010). This might be used to record comments like potential causes for the quality issue, or perhaps that the urgency of a stroke case meant that position optimization was intentionally skipped to obtain an image more quickly.

The Quality Reporter may record the identity of the person or device responsible for the Rejection/Quality Note in the Observer Context (Row 6 of TID 2010).

The Quality Reporter shall populate the Contributing Equipment Sequence (0018,A001), to the extent that these details are populated in the referenced image instance, with the Manufacturer, Manufacturer's Model Name, Software Versions, Device Serial Number, Station Name, Date of Last Calibration, Operators' Name and Operator Identification Sequence for the Acquisition Device and set the Purpose of Reference Code Sequence (0040,A170) to (109101, DCM, "Acquisition Equipment"). This is intended to support the Quality Analyzer doing basic analysis from the content of the KOS, without having to retrieve the referenced images unless needed for visual analysis.

When sending both the Rejection Note and the referenced images to the same Image Manager / Image Archive, it is good practice, but not required, that the Rejection Note be sent first. This avoids the situation where the Image Manager / Image Archive receives images but is not yet aware that they are rejected, and might inappropriately make them available for retrieval or perform automatic forwarding or notifications.

The Quality Reporter shall be configurable for how non-diagnostic images are handled. In an environment with a conformant Image Manager/Image Archive, the Quality Reporter may be configured to send non-diagnostic images to the Image Manager/Image Archive since it supports behavior to sequester such images (See Section X.1.1.3). In other environments, the Quality Reporter may be configured to send non-diagnostic images to a "Reject PACS" that is not part of the diagnostic reporting workflow, but is accessible to the image quality program so the images can be reviewed to understand the nature and causes of the quality problems. The Quality Reporter shall support configuration of an alternate destination for this purpose. The Quality Reporter may also be configured to discard non-diagnostic images.

The Quality Reporter is responsible for delivery of KOS instances to the destinations despite intermittent connections (e.g., due to network trouble, or the destination being down).

The Quality Reporter shall be capable of creating KOS instances for patient studies and for phantom/calibration studies.

Note: For phantom or calibration studies, it is expected that Quality Control Subject (0010,0200) will be present with a value of YES.

This profile does not distinguish between a Quality Reporter that is driven by human assessment, or by AI (for example, flagging excessive noise or body part mismatch), or some combination of the two. The identity of the human or algorithm may be recorded in the Observer Context as described above.

X.1.1.1.1 General

The two tables in this section include broad reason codes and detailed reason codes that are generally applicable across most modalities. The subsequent sections include detailed codes that are modality-specific.

Table X.1.1.1.1-3: Broad Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
DCM	111213	No image	"No evidence of a patient exposure" E.g. due to unexposed or faulty plate.
IHE		Wrong body part	The anatomy in the image does not match the anatomy indicated in the order. Note: ensure the image metadata correctly describes the imaged anatomy. Local policies typically call for such images to be read, so they will not be rejected and removed from the workflow. If the ordered anatomy is partially present, use code for Patient Positioning.
DCM	111209	Wrong patient positioning	The appearance of the image indicates the patient was not prepared and/or positioned as required for the procedure. E.g. weightbearing vs. non-weight bearing, upright vs. supine vs prone vs left-decubitus, etc. lateral vs. right-lateral <Need to update some DICOM code definitions to be less XR-specific>
IHE		Wrong view	The view for the acquired image is not correct.
IHE		Wrong protocol	The protocol used to acquire the image is not correct.
IHE		Wrong contrast	The timing, distribution, or presence of contrast media in the image is incorrect.
DCM	111210	Motion blur	Image blur due to relative motion between the anatomy of interest and the imaging equipment during acquisition which has been inadequately compensated for.
DCM	111207	Image artifacts	Signals are present that do not faithfully reproduce actual anatomic structures because of distortion, addition, or deletion of information.
IHE		High noise	The noise in the image is undesirably high.

Coding Scheme	Code Value	Code Meaning	Notes
			This might be due to poor technique parameters, non-optimized image processing, or patient characteristics
IHE		Poor dynamic range	The dynamic range of the pixels (sometimes referred to as contrast) is too narrow or is shifted. This might be due to poor technique parameters or nonoptimized image processing.
			<Do we need a general incorrect equipment usage code?>
IHE		Equipment issue	Power failure; unexpected detector disconnection; other unexpected mechanical or software failure <Should this be removed since it is more cause than observable?>
IHE		Redundant Image	The image largely duplicates the content of other images, and thus provides no additional clinical information. Some site policies might use this as a rejection reason to "declutter" the reading workflow. Other sites might use it as a quality reason to keep it available to the radiologist but flag the redundancy for quality improvement.
		Procedural image? (was Practitioner-directed)	Imaging under the direct guidance of a practitioner might result in images rejected as redundant, having no clinical relevance after the procedure is completed. Example: positioning devices such as feeding tubes using mobile radiography. <Q. Is Rejection the right mechanism to handle this?>

Notes: 1. The above IHE codes are provided for use in Trial Implementation. They will be replaced with DICOM and/or LOINC codes in Final Text.

2. Identifying wrong patient issues is addressed by the IHE Image Object Change Management (IOCM) Profile.

Table X.1.1.1.1-4: Detailed Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
IHE		Incomplete Anatomic coverage	The required anatomy not fully visualized in the image (i.e. "cut off"). Causes may include anatomy obscured by collimation; detector-tube alignment; orthopedic fixation device not visible. (sometimes the imaging target is not anatomy, it can be/include an implant)
IHE		Wrong Anatomic orientation	The image "Rotation/tilt" Image orientation Causes may include incorrect anatomy rotation; incorrect tube angle; internal vs. external rotation (e.g. shoulder rotated in the wrong direction).
IHE		Mislabeled Image	The metadata, such as the view, anatomy, patient positioning, do not correspond to the image.
IHE		"Voluntary" Motion	Patient moved during acquisition; did not follow breathing instructions

Coding Scheme	Code Value	Code Meaning	Notes
IHE		"Involuntary" Motion	Patient condition prevented compliance. Spasms, cough. Patient unable to understand or follow instructions due to age or language barrier.
IHE		"Known object"	Clinically relevant anatomy obscured by known objects (or resulting image artifacts) such as patient buttons, jewelry, etc.; O2 Line; positioning device, improper shield placement.
IHE		"Nonuniformity or defect visible"	Electromagnetic interference artifacts; detector artifacts such as dead pixels or lines; x-ray tube artifacts such as inverse-pinhole
IHE		"Saturation/ Overexposure"	Pixel clipping
IHE		Lack of Contrast	Lack of visible contrast media in a contrast-labelled image, possibly due to extravasation at the injection site.

X.1.1.1.2 Radiography

The codes in Table X.1.1.1.2-1 supplement those in Section X.1.1.1.1 to address quality issues specific to radiography images.

Table X.1.1.1.2-1: Detailed Radiography Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
DCM	111211	Under exposed	X-ray technique factors
DCM	111212	Over exposed	X-ray technique factors
DCM	111208	Grid artifact(s)	"Grid lines or similar artifact"
IHE		"Grid use error"	Erroneous use or nonuse of grid, wrong SID
IHE		"Detector not correctly selected or initialized"	Incorrect detector selected; no detector selected; bucky not pushed in far enough to initialize detector *Note: For some retro-fit systems, an exposure button press may not produce an image. See sec. IV.B*

X.1.1.1.3 Mammography

The codes in Table X.1.1.1.3-1 supplement those in Section X.1.1.1.1 to address quality issues specific to ultrasound images.

Table X.1.1.1.3-1: Detailed Mammography Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
IHE			
IHE			

X.1.1.1.4 Angiography/Fluoroscopy

The codes in Table X.1.1.1.4-1 supplement those in Section X.1.1.1.1 to address quality issues specific to ultrasound images.

Table X.1.1.1.4-1: Detailed Angiography/Fluoroscopy Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
IHE			
IHE			

X.1.1.1.5 CT

The codes in Table X.1.1.1.5-1 supplement those in Section X.1.1.1.1 to address quality issues specific to ultrasound images.

Table X.1.1.1.5-1: Detailed CT Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
IHE			
IHE			

X.1.1.1.6 Ultrasound

The codes in Table X.1.1.1.6-1 supplement those in Section X.1.1.1.1 to address quality issues specific to ultrasound images.

Table X.1.1.1.6-1: Detailed Ultrasound Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
IHE			
IHE			

X.1.1.1.7 Nuclear Medicine

The codes in Table X.1.1.1.7-1 supplement those in Section X.1.1.1.1 to address quality issues specific to nuclear medicine images.

Table X.1.1.1.7-1: Detailed Nuclear Medicine Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
IHE		Visible Extravasation	The radiopharmaceutical appears to have been injected into tissues.
IHE		Insufficient Counts	The number of acquired counts is below the threshold normally required to create a good image.

X.1.1.1.8 MR

The codes in Table X.1.1.1.8-1 supplement those in Section X.1.1.1.1 to address quality issues specific to MR images.

Table X.1.1.1.8-1: Detailed MR Reason Codes

Coding Scheme	Code Value	Code Meaning	Notes
IHE		Room Interference	<mostly for portable units. What is the observed feature? Otherwise this feels like a cause>
IHE		Uneven Fat Saturation	The appearance of patches or streaks where fat appears brighter due to uneven saturation by the pre-pulse. This may be caused by issues with the magnetic field, patient motion, or scan parameters.
IHE		Phase Wrap	Superposition of anatomy outside the field of view on anatomy inside the field of view.
IHE		Incorrect Coil Usage	E.g. activating all the coils in a long spine coil when scanning a short patient
IHE		Geometric Distortion	Warping or misshaping of some or all of the imaged anatomy.

X.1.1.2 Quality Analyzer

Quality Analyzers receive and/or retrieve rejection and quality information (KOS instances) and are expected to support some sort of review process and/or present some form of report to the user based on that information.

The format, contents and analysis of such reports are not defined by the IHE. Such details should be worked out as part of the product design. Examples might include generating a daily or weekly breakdown of rejections, or detailed review of individual rejection cases. See Section X.4.1.3 Analysis & Reporting.

The identity of the acquisition device, and the identity of the technologist performing the acquisition, are potential sources of quality issues and thus are key data elements to include in the quality analysis. These and other relevant details may be available to the Quality Analyzer in the headers of the images referenced in the KOS instances. The attributes of the General Equipment Module in the images will reflect the acquisition device. When the Rejection Note or Quality Note is created on a QC workstation, the PACS, or during reporting, the attributes of the General Equipment Module in the KOS instances will reflect that device not the acquisition device.

Having accurate information in the image headers about the technologist will typically depend on them making the acquisition device aware when the operator changes. This is not always the case in some sites. An analyzer might obtain this information from other sources, such as interacting or integrating with the RIS to access details about who completed the study, but no standard interface is currently available to achieve this.

An analyzer may also choose to retrieve and analyze some of the KOS instances created by the Image Object Change Management (IOCM) Profile. KOS with a title of (113037, DCM, "Rejected for Patient Safety Reasons") or (113038, DCM, “Incorrect Modality Worklist Entry”) would potentially be relevant. KOS with a title of (113039, DCM, “Data Retention Policy Expired”) would likely not be of interest.

X.1.1.3 Image Manager / Image Archive

Image Manager / Image Archives store and manage rejection information (KOS instances) as part of the imaging record.

Images referenced by the Quality Reporter using KOS with a Document Title of "Rejected for Quality Reasons" are considered non-diagnostic and should not be visible in the clinical process. The sequestration behaviors that the Image Manager / Image Archive is required to support are described in RAD TF-2: 4.66.4.1.2. Briefly, this involves hiding the rejected instances in subsequent Query/Retrieve responses unless the client uses special mechanisms to bypass this behavior. An Image Manager / Image Archive implementation of the IOCM Profile is adequate for conformance to the RAM Profile.

Images referenced by the Quality Reporter using KOS with a Document Title of "Quality Issue" are considered to be diagnostic and are handled by the Image Manager / Image Archive the same as if they were not flagged.

X.1.1.4 Image Display

Image Displays used for reject analysis display images referenced in Rejection Notes and Quality Notes to help reviewers better understand the nature of the quality issue and possibly help determine the root cause.

To prevent inadvertent use of rejected images in clinical workflow, the rejected images may be sequestered by the Image Manager / Image Archive or may be moved to a different location than the clinical archive.

The Image Display shall be configurable to access an alternate AE Title. That AE Title may be provided by the Image Manager / Image Archive to expose rejected instances (See RAD TF-2: 4.66.4.1.3) or it may be the AE Title of the "Reject PACS" (See Section X.1.1.1).

X.2 RAM Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table X.2-1. Dependencies between options, when applicable, are specified in notes.

Table X.2-1: Reject Analysis & Monitoring – Actors and Options

Actor	Option Name	Reference
Quality Reporter	No options defined	
Quality Analyzer	No options defined	
Image Manager / Image Archive	No options defined	

Actor	Option Name	Reference
Image Display	No options defined	

X.3 RAM Required Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile ***in addition to all*** of the requirements for the grouped actor (Column 2) (Column 3 in alternative 2).

Section X.5 describes some optional groupings that may be of interest for security considerations and Section X.6 describes some optional groupings in other related profiles.

Table X.3-1: Reject Analysis & Monitoring – Required Actor Groupings

RAM Actor	Actor(s) to be grouped with	Reference
Quality Reporter	ITI Consistent Time / Time Client	ITI TF-1: 7.1
	RAD Radiation Exposure Monitoring / Acquisition Modality (See Note 1)	RAD TF-1: 22.1
Quality Analyzer	None	--
Image Manager / Image Archive	None	--
Image Display	None	--

Note: 1. This grouping is only required if the Quality Reporter is an acquisition modality that uses X-rays.

X.4 RAM Overview

X.4.1 Concepts

X.4.1.1 Rejection Notes and Quality Notes

A Rejection Note is a way of maintaining a record of the rejection of DICOM images. It is encoded as an instance of a DICOM Key Object Selection (KOS) object. The KOS captures a list of image instances and associated metadata about the rejection of those instances (e.g. the reason that the instances have been rejected). A Rejection Note can be distinguished from other KOS instances by the document title of the TID 2010 container, which is (113001, DCM, "Rejected for Quality Reasons").

The presence of a Rejection Note may result in the Image Manager/Image Archive sequestering the referenced images so those are not used clinically. See X.1.1.3 for more details. It is not uncommon for rejected images to be retained for medicolegal reasons as well as quality review.

A Quality Note is a way of maintaining a record of quality issues identified in DICOM images. Quality issues differ from rejections in that the images are still considered diagnostic and are included in the clinical workflow. It is also encoded as an instance of a DICOM KOS object. A

Quality Note can be distinguished from other KOS instances by the document title of the TID 2010 container, which is (113010, DCM, "Quality Issue").

Both Rejection Notes and Quality Notes include one or more Document Title Modifier codes to describe the reason the images were labelled as being rejected or having a quality issue. Many reason codes, for example (111212, DCM, "Over exposed") could be appropriately used in either a Rejection Note (indicating that the over-exposure is sufficiently severe that the image is non-diagnostic) or a Quality Note (indicating that the image is diagnostic but the degree of over-exposure is undesirable/sub-optimal and ideally would be avoided in the future). A given image might be referenced by one or more Rejection Notes and one or more Quality Notes, indicating that multiple issues were observed, some of which would not have otherwise resulted in the image being rejected, but due to other issues, it was.

Since the KOS instances are persistently stored by the Image Manager/Image Archive in the corresponding Study folders, they are available for querying, retrieval, and analysis as part of record keeping and in support of quality control processes.

X.4.1.2 Codesets

For sites to analyze reject and quality records and use them to drive QA processes, it is critical to use standard codesets in a consistent fashion for imaging procedure codes and quality reasons.

This profile does not mandate the use of particular codesets, so agreeing within the local site or organization on common codesets will be a prerequisite for effective deployment of this profile.

Sections under X.1.1.1 provide recommended quality codesets.

Note: Sites that prefer a synonymous meaning that still matches the definition for the code can configure systems to use the synonym without degrading their interoperability by using an entirely different code.

X.4.1.3 Analysis & Reporting

The motivation for analysis and reporting of rejection and quality notes is to maintain and/or improve the quality of imaging services. The goals include to minimizing risks and physical impact on patients, and lowering procedure costs.

Quality notes may indicate issues that made it harder or slower for the imaging clinician to interpret the image, may have resulted in a slower or less complete exam, or may have used higher than desired radiation. In the case of rejection notes, imaging may have needed to be repeated, negatively impacting the timeliness of care, the efficiency of the department, the comfort of the patient, and potentially introducing additional radiation risks. Or if imaging was not repeated, there was an absence of potentially important diagnostic information.

Reject rates that are too high may indicate inefficient workflows and, depending on the imaging modality, unnecessary radiation exposure to the patient. Too few rejected images or identified quality issues may indicate a lack of quality control and the fact that suboptimal images are being sent to the radiologist for interpretation.

A key benefit of the profile is that both rejection and quality data is centrally aggregated for issues identified at all conformant modality devices, and for issues identified at acquisition, during QA or during review.

It is expected that site quality programs will involve monthly review by stakeholders such as the lead technologists, physicists, and department administrators.

The profile does not mandate, but is intended to facilitate, the ability of a Quality Analyzer to do things like:

- tabulate the frequency of each quality issue and reason for rejection, overall and organized by individual modality device/room, operator/technologist, work shift, location (inpatient/outpatient/ER/OR/portable/ortho/etc.), protocol/procedure type, and facility (if the review spans multiple sites).
- assist in identifying trends through interactive plots and summary statistics, for example month to month, year to year, before/after a quality program intervention, or score relative to an established target.

  Note: the analyzer likely maintains past statistics, so it would typically always query for the latest month of Rejection Notes and Quality Notes rather than retrieving an entire year's worth.
- drill down analysis by procedure, location, device, technologist, etc., displaying associated images and metadata and assisting the determination of the root cause of a given quality issue or rejection.
- facilitate access to the images when necessary to better understand a specific issue.
- support random sampling of "good" (i.e. unflagged) images for a given procedure, device, technologist, or shift to assess whether the initial QA phase is sufficiently sensitive.
- break out notes created by the imaging clinicians during interpretation as indicating issues that made it past initial QA.
- potentially identify rejections or quality issues that are being "overcalled" (i.e., flagging images that are within the established acceptable quality range as having an issue, perhaps out of a desire to always produce "textbook images")
- enable detailed analysis of protocol parameters and system use. Examples in radiography include exposure index (EI) analysis, automatic exposure control (AEC) performance, and image processing parameter optimization. Additional information for radiography is available in [citation to TG305].

The analysis is intended to help guide remediation steps to avoid the rejection or quality issues in the future.

- targeted technologist education. For example, if knee images are not coming out well due to poor positioning, a tech or group of techs might be given training on positioning techniques, potentially using the Rejection Note tagged images as teaching aids. Subsequent reporting might indicate the success/impact of the remediation.

- device service. For example, certain artifacts might indicate equipment that is degraded and in need of repair or re-calibration.
- revise or clarify policies, procedures, and protocols
- Radiologists can be assisted in determining how changes in techniques and protocols impact diagnostic ability.

Data will generally be continuously collected for all imaging procedures. Periodic process improvement and data analysis would focus on local variations attributable to x-ray equipment, operators, procedures, and ordering physicians. The RAM Profile does not define purpose of analysis, analytical methods, and other usage.

X.4.2 Use Cases

X.4.2.1 Use Case #1: Rejection

The Reject Case involves rejecting an image (non-diagnostic) and storing rejection information for later quality management use.

X.4.2.1.1 Rejection Case Description

Typically, acquired images are checked for quality at the time of acquisition, or shortly thereafter as part of a QA step. An image that is determined to be non-diagnostic is "rejected" and is not sent for interpretation. Acquisition of a "repeat" image, to replace the rejected image, may take place.

Notes: 1. Quality issues that do not prevent the image from being interpreted are discussed in Section X.4.2.2 Use Case 2.

2. In current practice, if the image is checked but no quality issues are observed, the workflow proceeds as normal and there is no record of the review.

Image rejection most commonly occurs at the modality. Rejection can also occur during image interpretation. An image marked as a quality issue (See Use Case 2) by the technologist might later be judged non-diagnostic and rejected by the radiologist. More specifically, this may occur when the tech observes an artifact that they are unable to avoid so they tag the quality issue and leave it to the radiologist to decide if it is usable. Note that this can result in two KOS for the same image, which the Quality Analyzer should be prepared to handle.

In other cases, particularly for modalities that do not involve ionizing radiation, the technologist might observe a quality issue that can be improved so they retake the image and the original is Rejected to keep it out of the flow.

While rejected images should not be used clinically, it is highly desirable to retain the images for review during the quality management process, since inspection of the image can be very helpful in understanding the characteristics and cause of the quality failure. It is also possible that review determines the rejected image was usable or that it would have been possible to process the image to make it usable. Such findings can lead to process improvements. Examining the images can also help distinguish between a repeated acquisition that was needed to replace the original, or to supplement the original (e.g. the anatomy was too large to fit in a single image). Some

reject-repeats are due to technologist misjudgments, while others are unavoidable (e.g. patient motion, or the patient forgot about jewelry they were wearing when asked).

X.4.2.1.2 Rejection Case Process Flow

Figure X.4.2.1.2-1 shows a Quality Reporter grouped with the Acquisition Modality. Alternatively, the Acquisition Modality could send the acquired images to a Quality Reporter in a separate QA workstation.

Radiation dose information associated with the acquired images is shown being stored by the Quality Reporter and retrieved by the Quality Analyzer for use in the Quality Review Process, however that analysis is optional (and would not exist for modalities like MR and ultrasound).

Alternatively, there could be a Quality Reporter on a workstation between the Modality and the Image Manager / Image Archive, or on the Image Manager / Image Archive itself, or on the radiology reading workstation.

Note that when the Quality Analyzer retrieves the rejected images referenced in the Rejection Note for use in the Quality Review Process, it uses the mechanism to bypass the Sequestration behavior of the Image Manager / Image Archive (see RAD TF-2: 4.66.4.1.3.1) which would be hiding the rejected images from normal use.

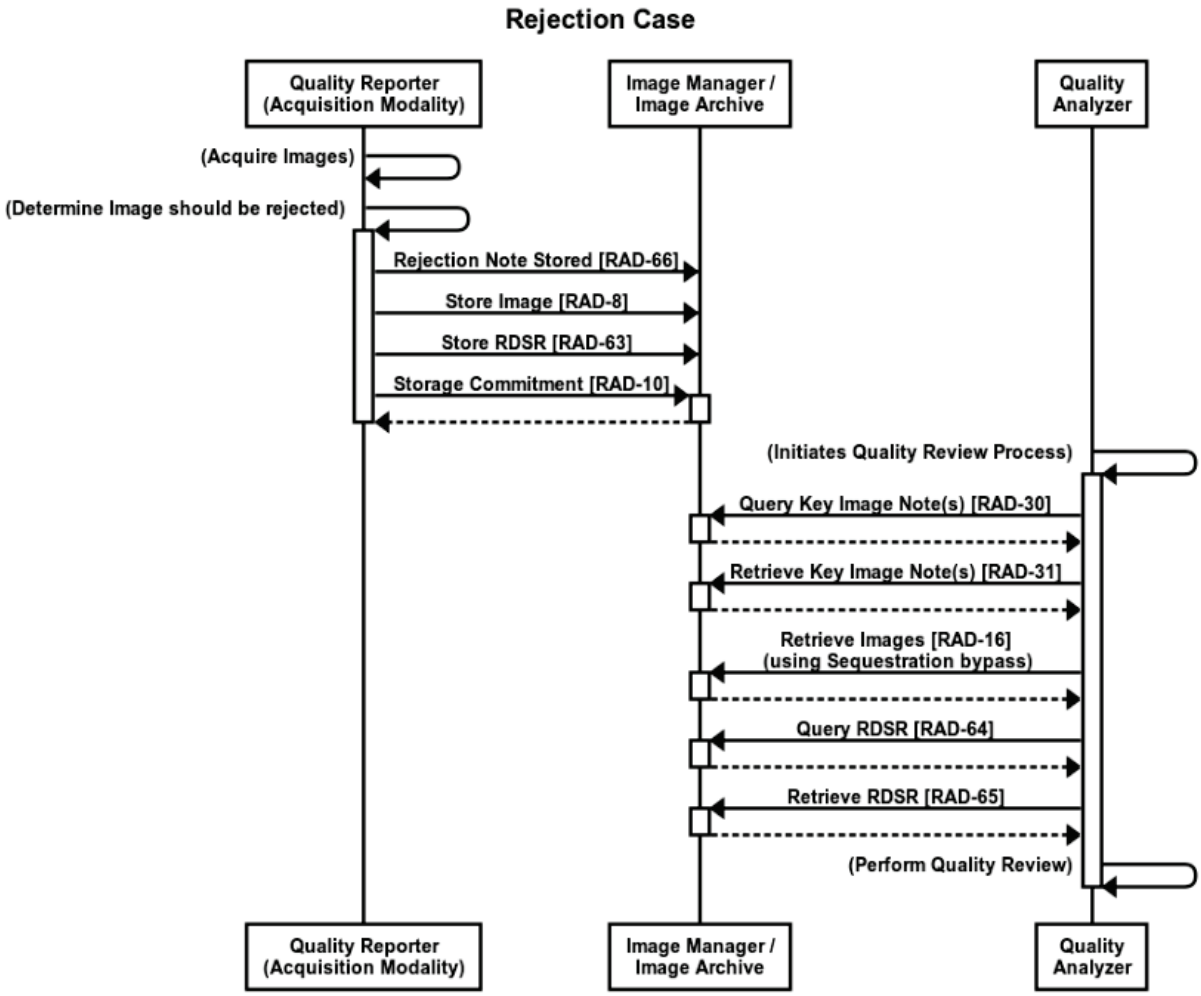


Figure X.4.2.1.2-1: Rejection Process Flow

The text in Figure X.4.2.1.2-2 was used to generate the diagram in Figure X.4.2.1.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.


```
title Rejection Case

participant Quality Reporter\n(Acquisition Modality) as QR
participant Image Manager /\nImage Archive as IMIA
participant Quality\nAnalyzer as QA

QR->QR: (Acquire Images)
QR->+QR: (Determine Image should be rejected)
QR->IMIA: Rejection Note Stored [RAD-66]
QR->IMIA: Store Image [RAD-8]
QR->IMIA: Store RDSR [RAD-63]
QR->+IMIA: Storage Commitment [RAD-10]
IMIA-->-QR:
deactivate QR

QA->+QA: (Initiate Quality Review Process)
QA->IMIA: Query Key Image Note(s) [RAD-30]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve Key Image Note(s) [RAD-31]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve Images [RAD-16]\n (using Sequestration bypass)
activate IMIA
IMIA-->-QA:
QA->IMIA: Query RDSR [RAD-64]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve RDSR [RAD-65]
activate IMIA
IMIA-->-QA:
QA->-QA: (Perform Quality Review)
```

Figure X.4.2.1.2-2: Diagram Pseudocode for Rejection Process Flow

X.4.2.2 Use Case #2: Quality Issue

The Quality Issue Case involves labelling an image as having a quality issue and storing that information for later quality management use.

Note: Non-diagnostic (rejected) images are discussed in Section X.4.2.1 Use Case 1.

X.4.2.2.1 Quality Issue Description

Images checked for rejection as described in Section X.4.2.1 may also be found to have quality issues. While the image is sub-optimal, it is still considered to be diagnostic and proceeds through the clinical workflow as usual.

The diagram here shows the image being labelled during a post-acquisition quality assessment step on a QA workstation. The study would typically be "completed" in the RIS by the QA tech after the QA review is complete. If there are no quality issues, the QA Workstation would forward the images to the Image Manager /Image Archive without creating a Quality Note.

Additionally, quality labels might be applied by a reviewer at the Acquisition Modality, the Image Manager / Image Archive, or by the imaging clinician during image interpretation. Some issues noted by the reading clinician might include positioning, cropping, and exposure factors, etc.

The diagram shows the images being sent from the Acquisition Modality to the QA Workstation. Alternatively, the images might be sent directly from the Acquisition Modality to the Image Manager / Image Archive and they QA Workstation views the new images there before creating and storing Quality Notes as appropriate.

Quality Notes created at later steps would be stored similarly and also be made available as feedback to the techs and be analyzed during periodic quality reviews. Also not shown here is the possibility that the imaging clinician might consult the quality tags applied to the images during the QA step.

X.4.2.2.2 Quality Issue Process Flow

Figure X.4.2.2.2-1 shows a Quality Reporter grouped with the Acquisition Modality. Alternatively, the Acquisition Modality could send the acquired images to a Quality Reporter in a separate QA workstation.

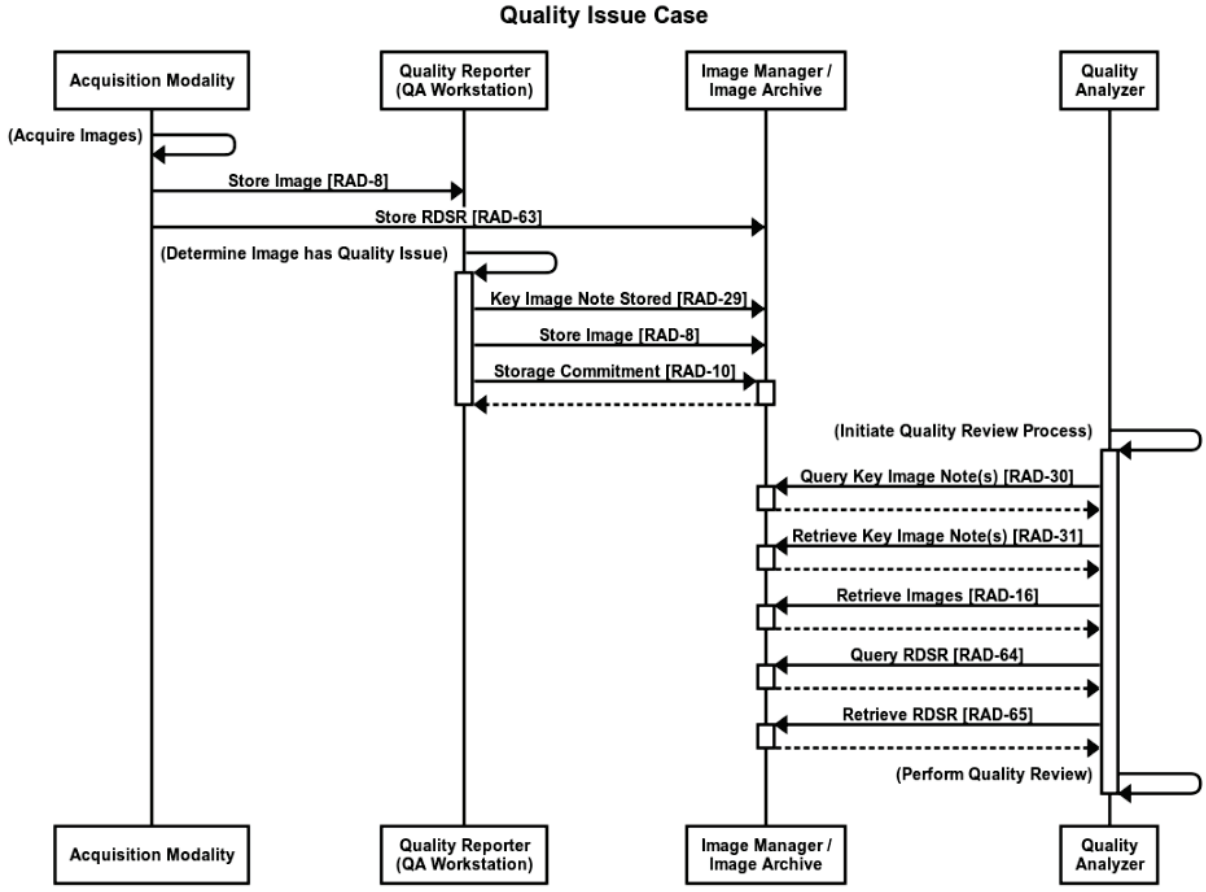


Figure X.4.2.2.2-1: Quality Issue Process Flow

The text in Figure X.4.2.2.2-2 was used to generate the diagram in Figure X.4.2.2.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.


```
title Quality Issue Case

participant Acquisition Modality as AM
participant Quality Reporter\n(QA Workstation) as QR
participant Image Manager /\nImage Archive as IMIA
participant Quality\nAnalyzer as QA

AM->AM: (Acquire Images)
AM->QR: Store Image [RAD-8]
AM->IMIA: Store RDSR [RAD-63]
QR->+QR: (Determine Image has Quality Issue)
QR->IMIA: Key Image Note Stored [RAD-29]
QR->IMIA: Store Image [RAD-8]
QR->+IMIA: Storage Commitment [RAD-10]
IMIA-->-QR:
deactivate QR

QA->+QA: (Initiate Quality Review Process)
QA->IMIA: Query Key Image Note(s) [RAD-30]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve Key Image Note(s) [RAD-31]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve Images [RAD-16]
activate IMIA
IMIA-->-QA:
QA->IMIA: Query RDSR [RAD-64]
activate IMIA
IMIA-->-QA:
QA->IMIA: Retrieve RDSR [RAD-65]
activate IMIA
IMIA-->-QA:
QA->-QA: (Perform Quality Review)
```

Figure X.4.2.2.2-2: Diagram Pseudocode for Quality Issue Process Flow

X.5 RAM Security Considerations

KOS instances contain PHI such as patient demographics. The security considerations are similar to those for images. It may also be appropriate to log the creation, query, and transfer of KOS instances using the Record Audit Event [ITI-20] transaction defined in the IHE ITI Audit Trail and Note Authentication (ATNA) Profile.

Since rejection notes can result in clinical images going unreviewed and potentially being deleted, security considerations should include determining which operators and systems are able to submit rejection notes. It may also be prudent for Image Manager / Image Archives to retain rejected images at least until local quality review has been completed.

Quality Reporters and Quality Analyzers are typically connected to the same data networks as imaging modality systems and should follow similar data protection practices, such as implementing the Authenticate Node [ITI-19] transaction in ATNA to enable secure connections.

X.6 RAM Cross-Profile Considerations

Since the data created and exchanged in the Reject Analysis & Monitoring Profile are encoded using common DICOM SR instances, many other Radiology profiles that manage content could be used in conjunction with the content of the RAM Profile:

- **Cross-Enterprise Document Sharing for Imaging (XDS-I.b)** and/or **Cross-Community Document Access for Imaging (XCA-I)** could be used to exchange quality information within and between enterprises
- **Import Reconciliation Workflow (IRWF.b)** and/or **Import and Display of External Priors (IDEP)** could be used to localize and manage the import of quality information
- **Portable Data for Imaging (PDI)** could be used to distribute quality information on portable media
- **Audit Trail and Node Authentication (ATNA)** (with the Radiology Audit Trail Option) is recommended to secure the communication of, and record audit trails for, quality information.
- **SWF.b – Scheduled Workflow.b** An Image Manager / Image Archive in SWF.b that also supports Reject Analysis and Monitoring is expected to reconcile the KOS instances along with the rest of the instances in a patient's study.

  Note: SWF.b addresses reconciliation driven by HL7 v2.5 messages. Reconciliation driven by HL7 v.2.3 messages is handled in the Patient Information Reconciliation (PIR) Profile which is used in concert with the original SWF Profile.

- **IOCM – Image Object Change Management**. A Change Requester in IOCM could be grouped with a Quality Reporter in RAM to handle both image quality issues and other workflow and patient safety issues.
  An Image Manager / Image Archive in IOCM could be grouped with an Image Manager / Image Archive in RAM to support awareness and sequestration of rejected images while making them available to quality review processes. The internal logic of the two profile behaviors is very similar.

Appendices to Volume 1

Not applicable

Volume 2 – Transactions

Modify Section 4.29 as shown

4.29 Key Image Note Stored [RAD-29]

4.29.1 Scope

~~**In the Key Image Note Stored**~~**This** transaction~~**, the Acquisition Modality or the Evidence Creator**~~ transmits a DICOM Key Image Note~~**, which is stored in the Image Archive**~~.

4.29.2 Actor Roles

The roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 4.29.2-1: Actor Roles

Role:	**Sender:** **Flags significant images by creating a Key Object Selection instance and sending it to the Receiver.**
Actor(s):	**The following actors may play the role of Sender:** **Acquisition Modality** **Evidence Creator**
Role:	**Receiver:** **Receives and stores Key Object Selection instances.**
Actor(s):	**The following actors may play the role of Receiver:** **Imager Manager / Image Archive**

~~**Actor: Acquisition Modality**~~

~~**Role: Flag significant images by creating Key Image Notes and issuing Key Image Note Stored Transactions to the Image Archive.**~~

~~**Actor: Evidence Creator**~~

~~**Role: Flag significant images by creating Key Image Notes and issuing Key Image Note Stored Transactions to the Image Archive.**~~

~~**Actor: Image Archive**~~

~~**Role: Accepts and Stores Key Image Note Instances received from the Acquisition Modality or Evidence Creator. This transaction describes the role related only to storage of the Key Image Note.**~~

4.29.3 Referenced Standards

DICOM PS3.3 Section A.35.4: Key Object Selection Document IOD

DICOM PS3.4 Annex B: Storage Service Class

DICOM PS3.16 TID 2010: Key Object Selection

4.29.4 Messages

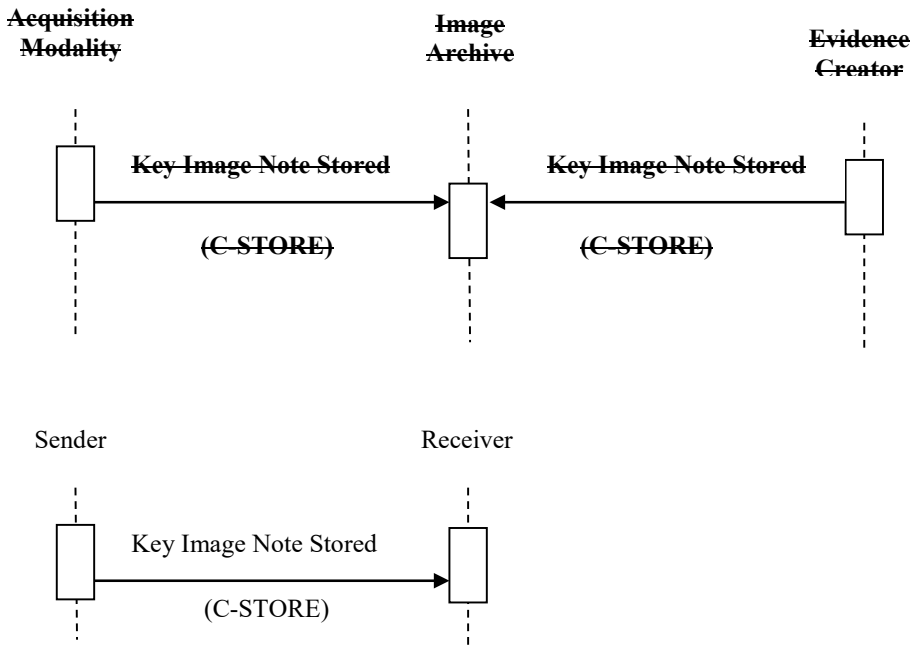


Figure 4.29.4-1: Interaction Diagram

4.29.4.1 Key Image Note Stored

~~**This transaction relates to the "DICOM C-STORE" event between the Acquisition modality or the Evidence Creator and the Image Archive in the above interaction diagram.**~~

4.29.4.1.1 Trigger Events

The **Sender**~~Acquisition Modality or the Evidence Creator generates~~ **determines that DICOM instances need to have particular labels applied and** a **corresponding** Key Image Note ~~and sends it to the Image Archive for~~ stor**ed**~~**e**~~**age**.

4.29.4.1.2 Message Semantics

The message is a DICOM C-STORE of a Key Object Selection instance. The Sender is the SCU. The Receiver is the SCP.

~~**The Acquisition Modality or the Evidence Creator uses the DICOM C-STORE message to store Key Image Notes.**~~

The Sender shall create a new~~**Message semantics are defined in the**~~ Key Object Selection Storage ~~**SOP Class definition and Behavior**~~**instance in a new Series of the referenced images' Study. Integration-critical values shall be filled as defined in the Evidence Document Attribute Mapping (RAD TF-2x: Appendix A.2). The instance shall be constructed as defined in**~~**section of**~~ DICOM PS3.3 and PS3.4.

The value of the Key Object Selection Document Title code and the Document Title Modifier code(s) may be constrained by the Profile invoking this transaction.

Key Object Selection Documents that reference multi-frame images shall populate the Referenced Frame Number (0008,1160) in each applicable occurrence of the Referenced SOP Sequence (0008,1199) in the Key Object Selection Document, unless the Key Object Selection Document applies to all the frames in the image.

4.29.4.1.3 Expected Actions

The **Receiver**~~**Image Archive**~~ will store the received Key Image Note objects.

Modify Section 4.66 to use the newer structure and add RAM details

4.66 Rejection Note Stored [RAD-66]

4.66.1 Scope

~~**In t**~~**T**his transaction **permits a Sender to**~~**, the Acquisition Modality, Change Requester or the Evidence Creator transmits a specific DICOM Key Object Selection (Rejection Note) to the Image Manager/Image Archive for**~~ mark**ing** referenced **instances**~~**images**~~ as "rejected"**, including**~~**. Beforehand, a user will have**~~:

- ~~**selected specific**~~ images ~~**to be**~~ rejected for quality reasons~~**, including**~~**(with** a reason for rejection**)**~~**, or**~~
- ~~**corrected certain images so that the original**~~ incorrect images ~~**are to be**~~ rejected for patient safety reasons~~**, or**~~

- ~~**associated certain images to the correct modality worklist entry so that the original**~~ images ~~**are to be**~~ rejected for incorrect modality worklist selection reason
- ~~**Alternatively, a user or the Image Manager/Archive selected specific**~~ instances to be deleted due to data retention policy expiration~~**, including**~~**(with** a reason for deletion**)**.

4.66.2 Actor Roles

The roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 4.66.2-1: Actor Roles

Role:	**Sender:** **Flags rejected images by creating a Rejection Note and sending it to the Receiver.**
Actor(s):	**The following actors may play the role of Sender:** **Acquisition Modality** **Evidence Creator** **Change Requester**
Role:	**Receiver:** **Receives and stores the Rejection Notes, and applies them by removing or sequestering the referenced images.**
Actor(s):	**The following actors may play the role of Receiver:** **Imager Manager/ Image Archive**

~~**Actor: Acquisition Modality**~~

~~**Role: Flags acquired available images that are incorrect or rejected for quality reasons by creating a Rejection Note and sending it to the Image Manger/ Image Archive.**~~

~~**Actor: Evidence Creator**~~

~~**Role: Flags images that are incorrect or rejected for quality reasons by creating a Rejection Note and sending it to the Image Archive.**~~

~~**Actor: Image Manager/ Image Archive**~~

~~**Role: Image Archive receives, processes and stores the Rejection Notes received from the Acquisition Modality, Evidence Creator or Change Requester. Image Manager/ Image Archive applies defined logic to the images that are referenced in the Rejection Note.**~~

~~**Actor: Change Requester**~~

~~**Role: Flags available instances that are (1) associated with an incorrect modality worklist entry, (2) expired for data retention policy or (3) rejected due to quality or patient safety reasons by creating a Rejection Note, and sending it to the Image Manager/Archive.**~~

4.66.3 Referenced Standards

DICOM PS3.3 Section A.35.4: Key Object Selection Document IOD

DICOM PS3.4 Annex B: Storage SOP Class

DICOM PS3.4 Annex C: Query/Retrieve SOP Class

DICOM PS3.16 TID 2010: Key Object Selection

DICOM PS3.16 CID 7011: Rejected for Quality Reasons

4.66.4 Messages

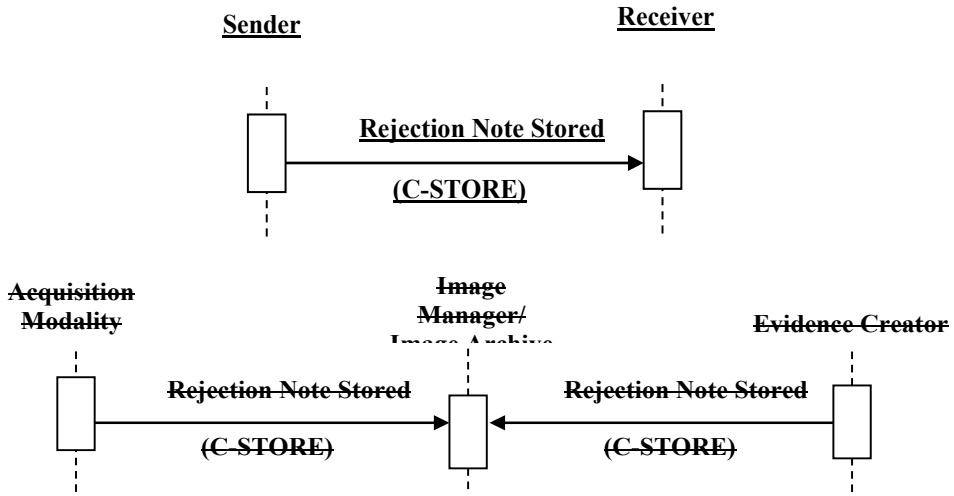
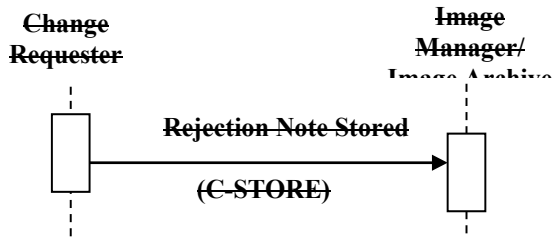


Figure 4.66.4-1: Interaction Diagram: Rejection Note Stored



~~**Figure 4.66.4-2: Interaction Diagram: Rejection Note Stored in IOCM**~~

~~**This transaction relates to the "DICOM C-STORE" event between the Acquisition Modality, the Evidence Creator, or the Change Requester and the Image Manager/Archive in the above interaction diagram. The Acquisition Modality, the Evidence Creator or the**~~

~~**Change Requester is the DICOM Storage SCU and the Image Manager/Archive is the DICOM Storage SCP.**~~

The following table summarizes Key Object Selection Document Titles usage in different IHE profiles:

Table 4.66.4-1: Profile Supported Key Object Selection Document Title

KOS Document Title	MAWF	IOCM	RAM	Section
(113001, DCM, "Rejected for Quality Reasons")	X	X	**X**	**4.66.4.1**
(113037, DCM, "Rejected for Patient Safety Reasons")	X	X		**4.66.4.2**
(113038, DCM, "Incorrect Modality Worklist Entry").		X		**4.66.4.3**
(113039, DCM, "Data Retention Policy Expired")		X		**4.66.4.4**

4.66.4.1 Rejection Note Stored (for Quality Reasons)

4.66.4.1.1 Trigger Events

An operator at the **Sender**~~**Acquisition Modality, the Evidence Creator or the Change Requester detects**~~ **determines** that certain images ~~**just acquired**~~ are of insufficient quality**,** **requiring that they be rejected**. ~~**She marks these images using the capability provided by the systems implementing these actors. Thereby, she generates a Rejection Note which the Acquisition Modality, Evidence Creator or the Change Requester sends to the Image Manager/Archive.**~~

4.66.4.1.2 Message Semantics

The message is a DICOM C-STORE of a Key Object Selection instance. The Sender is the SCU. The Receiver is the SCP.

The **Sender**~~**Acquisition Modality, Evidence Creator or Change Requester**~~ shall create a new Key Object Selection instance in a new Series of the rejected images' Study. Integration-critical values shall be filled as defined in the Evidence Document Attribute Mapping (RAD TF-2x: Appendix A.2). The instance shall be constructed as defined in DICOM PS3.3 and 3.4, and shall have ~~**the following values in the DICOM template TID 2010**~~:

- A Key Object Selection Document Title code of (113001, DCM, "Rejected for Quality Reasons").
- At least one Document Title Modifier code**. Unless otherwise specified by the profile invoking this transaction, the code(s) shall be drawn** from DICOM Context Group 7011.
- References to all rejected instances are specified as Content Items with value type of COMPOSITE, IMAGE or WAVEFORM in the Content Sequence (0040,A730).

4.66.4.1.3 Expected Actions

The **Receiver**~~**Image Manager/Archive**~~ receives the Key Object Selection **instance**~~**with the Document Title valued (113001, DCM, "Rejected for Quality Reasons")**~~ and shall store it. The **Receiver**~~**Image Manager/ Image Archive**~~ shall support the two behaviors listed below. The behavior chosen shall be configurable.

- **Expose Rejected Instances**~~**Regular use**~~: For the Key Object Selection instance and all instances referenced therein, the **Receiver**~~**Image Manager/Archive**~~ shall return SOP Instance UIDs in Query Responses and the instances in Patient, Study, Series, or Instance level retrievals.
- Hide **R**~~**r**~~ejected **I**~~**i**~~nstances: For the rejected instances referenced in the Key Object Selection, the **Receiver**~~**Image Manager/Archive**~~ shall neither return SOP Instance UIDs in Query Responses nor return the instances in Patient, Study, Series, or Instance level retrievals. If the request includes optional Additional Query/Retrieve Attributes defined in Table 4.66.4.1.3-1, then the returned value(s) of the requested attributes shall reflect the absence of hidden rejected instances.

Table 4.66.4.1.3-1: Additional Query/Retrieve Attributes

Attribute Name	Tag
Number of Patient Related Studies	(0020,1200)
Number of Patient Related Series	(0020,1202)
Number of Patient Related Instances	(0020,1204)
Number of Study Related Series	(0020,1206)
Number of Series Related Instances	(0020,1209)
Number of Study Related Instances	(0020,1208)
Modalities in Study	(0008,0061)
SOP Classes in Study	(0008,0062)
Alternate Representation Sequence	(0008,3001)

For example, the following study has two original series and a Rejection Note for Quality Reason that references all instances in Series 2

- Series 1: Modality = MR, 200 objects
- Series 2: Modality = US, 80 objects
- Series 3: Modality = KO (Rejection Note), 1 object (references all 80 objects in Series 2)

When the **Receiver**~~**Image Manager**~~ receives a C-FIND request for this study and the request specifies the additional Number of Study Related Series (0020,1206), Number of Study Related Instances (0020,1208) and Modalities in Study (0008,0061) attributes, then using the **Expose rejected instances**~~**Regular Use**~~ behavior, the **Receiver**~~**Image Manager**~~ will return the following result with respect to the additional Query/Retrieve attributes:

Table 4.66.4.1.3-2: Expose Rejected Instances~~Regular Use~~ Behavior - Example Attribute Values

Attribute Name	Value
Number of Study Related Series	3
Number of Study Related Instances	281
Modalities in Study	MR \ US \ KO

When using the Hide Rejected Instances behavior, the **Receiver~~Image Manager~~** will return the following result with respect to the additional Query/Retrieve attributes:

Table 4.66.4.1.3-3: Hide Rejected Instances Behavior - Example Attribute Values

Attribute Name	Value
Number of Study Related Series	3 if empty series is returned, or 2 if empty series is not returned
Number of Study Related Instances	201
Modalities in Study	MR \ KO

If the complete series is rejected according to the specified behavior as described above, then the **Receiver~~Image Manager/Archive~~** may or may not return the empty series in the C-FIND response when it receives a SERIES level C-FIND request.

4.66.4.1.3.1 Access to Rejected Instances

The contents of this section are required for **Receiver~~Image Manager/Archive~~** Actors in the Imaging Object Change Management Profile.

The **Receiver~~Image Manager/Archive~~** shall provide two Application Entities for each C-FIND service and each C-MOVE service; one AE associated with the **Expose Rejected Instances~~Regular Use~~** behavior, and one AE associated with the Hide Rejected Instances behavior (see Section 4.66.4.1.3).

The **Receiver~~Image Manager/Archive~~** shall be configurable to restrict access to the **Expose Rejected Instances~~"Regular Use"~~** Application Entity to a limited set of calling AE Titles.

4.66.4.2 Rejection Note Stored (for Patient Safety Reasons)

4.66.4.2.1 Trigger Events

An operator at the **Sender~~Acquisition Modality, the Evidence Creator or the Change Requester detects~~** **determines** that certain ~~**just acquired**~~ images or ~~**just created**~~ evidence documents are incorrect. ~~**She corrects these images or evidence documents using the capability provided by the systems implementing these actors. Thereby, she generates a**~~

~~**Rejection Note which the Acquisition Modality, Evidence Creator or Change Requester sends to the Image Manager/Archive.**~~

4.66.4.2.2 Message Semantics

The message is a DICOM C-STORE of a Key Object Selection instance. The Sender is the SCU. The Receiver is the SCP.

The **Sender**~~**Acquisition Modality, the Evidence Creator or the Change Requester**~~ shall be able to let a user correct one or more attributes in images that are displayed or in evidence documents that are applied.

- The user shall be able to store new, corrected images or evidence documents at the Acquisition Modality as defined in Section 4.8.4.1.2 or at the Evidence Creator as defined in Section 4.18.4.1.2.

The **Sender**~~**Acquisition Modality, Evidence Creator or Change Requester**~~ shall create a new Key Object Selection instance in a new Series of the **rejected**~~**incorrect**~~ instances' Study. Integration-critical values shall be filled as defined in the Evidence Document Attribute Mapping (RAD TF-2x: Appendix A.2). The instance shall be constructed as defined in DICOM PS3.3 and 3.4, and shall **have**:

- ~~**Have the**~~**A** Key Object Selection Document Title **code of**~~**value**~~ (113037, DCM, "Rejected for Patient Safety Reasons")
  - References to all incorrect instances and derived instances (e.g., FOR PRESENTATION and FOR PROCESSING) ~~**are specified**~~ as Content Items with value type of COMPOSITE, IMAGE or WAVEFORM in the Content Sequence (0040,A730).

This Key Object Selection instance shall be stored to the **Receiver** ~~**Image Manager/Archive**~~. It serves as a trigger to disallow routine use of these incorrect instances that it references.

4.66.4.2.3 Expected Actions

The **Receiver**~~**Image Manager/Archive**~~ receives the Key Object Selection ~~**(KOS)**~~ instance ~~**with the Document Title value (113037, DCM, "Rejected for Patient Safety Reasons")**~~ and shall store it.

The **Receiver**~~**Image Manager/Archive**~~ shall hide the referenced ~~**incorrect**~~ instances and specifically shall not provide the**se** ~~**incorrect**~~ instances in responses to an image query/ retrieve transaction [RAD-14**]**, **[**RAD-16] or presentation state query/retrieve transaction [RAD-15], [RAD-17].

If the complete series is rejected, then the **Receiver**~~**Image Manager/Archive**~~ may or may not return the empty series in the C-FIND response when it receives a SERIES level C-FIND request.

4.66.4.2.3.1 Additional Requirements for Image Manager/Archive in IOCM

The **Receiver**~~**Image Manager/Archive**~~ shall not accept subsequent occurrence of instances that have been hidden.

4.66.4.3 Rejection Note Stored (for Incorrect Modality Worklist)

4.66.4.3.1 Trigger Events

An operator at the Sender~~**Change Requester (grouped with an Acquisition Modality or Image Manager/Archive) detects**~~ **determines** that certain images**, typically** just acquired and transmitted**,** are associated with an incorrect modality worklist entry. ~~**She corrects the images to the correct modality worklist entry using the capability provided by the systems implementing these actors. Thereby, she generates a Rejection Note and sends it to the Image Manager/Archive.**~~

4.66.4.3.2 Message Semantics

The message is a DICOM C-STORE of a Key Object Selection instance. The Sender is the SCU. The Receiver is the SCP.

The **Sender**~~**Change Requester**~~ shall enable a user to associate one or more objects in the study with the correct modality worklist entry. The **Sender**~~**Change Requester**~~ shall create a new Key Object Selection instance in a new Series of the study referencing the **rejected** instances associated with the incorrect modality worklist entry. Integration-critical values shall be filled as defined in the Evidence Document Attribute Mapping (RAD TF-2x: Appendix A.2). The instance shall be constructed as defined in DICOM PS3.3 and 3.4, and shall have ~~**the following values in the DICOM template TID 2010**~~:

- A Key Object Selection Document Title code of (113038, DCM, "Incorrect Modality Worklist Entry").
- References to all instances associated with the incorrect modality worklist entry ~~**are specified**~~ as Content Items with value type of COMPOSITE, IMAGE or WAVEFORM in the Content Sequence (0040,A730).

4.66.4.3.3 Expected Actions

The **Receiver**~~**Image Manager/Archive**~~ receives the Key Object Selection ~~**(KOS)**~~ instance ~~**with the Document Title values (113038, DCM, "Incorrect Modality Worklist Entry")**~~ and shall store it.

The **Receiver**~~**Image Manager/Archive**~~ shall hide the **referenced**~~**incorrect**~~ instances and specifically shall not provide the**se** ~~**incorrect**~~ instances ~~**referenced in this KOS**~~ in responses to an image query/retrieve transaction [RAD-14], [RAD-16] or presentation state query/retrieve transaction [RAD-15], [RAD-17].

The **Receiver**~~**Image Manager/Archive**~~ shall not accept subsequent occurrence of instances that have been hidden.

If the complete series is rejected, then the **Receiver~~Image Manager/Archive~~** may or may not return the empty series in the C-FIND response when it receives a SERIES level C-FIND request.

4.66.4.4 Rejection Note Stored (for Data Retention Expiry)

4.66.4.4.1 Trigger Events

A manual or automatic procedure in the **Sender~~Change Requester (grouped with Image Manager/Archive)~~** determines that certain instances exceed the required period of data retention and automatically deletes them locally and**~~. B~~ b**ased on configuration, **determines that~~the Change Requester communicates the expiry of instances to~~** an external Image Manager/Archive (e.g., Centralized Archive) **should be notified**. **~~Thereby, it generates a Rejection Note and sends to the external Image Manager/Archive.~~**

4.66.4.4.2 Message Semantics

The message is a DICOM C-STORE of a Key Object Selection instance. The Sender is the SCU. The Receiver is the SCP.

The **Sender~~Change Requester~~** shall create a new Key Object Selection instance in a new Series for each study with the expired instances. Integration-critical values shall be filled as defined in the Evidence Document Attribute Mapping (RAD TF-2x: Appendix A.2). The instance shall be constructed as defined in DICOM PS3.3 and 3.4, and shall have **~~the following values in the DICOM template TID 2010~~**:

- A Key Object Selection Document Title code of (113039, DCM, “Data Retention Policy Expired”).
- References to all instances within the study that have exceeded the required data retention period **~~are specified~~** as Content Items with value type of COMPOSITE, IMAGE or WAVEFORM in the Content Sequence (0040,A730).

4.66.4.4.3 Expected Actions

The **Receiver~~Image Manager/Archive~~** receives the Key Object Selection **~~(KOS)~~** instance **~~with the Document Title values (113039, DCM, “Data Retention Policy Expired”)~~** and shall store it.

The **Receiver~~Image Manager/Archive~~** will decide, depending on its local data retention policies, whether to act **~~on the information in the KOS~~** and how to act. If it chooses to act **~~on the KOS~~**, it may delete the **referenced~~expired~~** instances **~~referenced in the KOS~~**.

If the complete content of a series is deleted, the **Receiver~~Image Manager/Archive~~** may or may not also delete the series itself.

If the **Receiver~~Image Manager/Archive~~** later receives instances that have been previously deleted due to the expiry of data retention period and not deleted due to other reasons, then the

Receiver~~Image Manager/Archive~~ may choose to decide that the Data Retention Policy Expired rejection is no longer in force. If it so decides, it shall:

- store the instances as defined in one of the corresponding instance stored transactions [(RAD-8], [RAD-9], [RAD-18], [RAD-19], [RAD-29], [RAD-43], [RAD-61])**,**
- return the referenced instances in subsequent query or retrieve requests**, and**
- not return the Rejection Note corresponding to the Data Retention Policy Expired rejection that is no longer in force

